JUL - 9 2001

K003254

510(k) Summary Date: 10/10/2000

1. Submitter Information

Mr. Donald V. Canal
Mission Medical Devices
3525 Del Mar Heights Road #430
San Diego, Ca 92130

2. Name of Device

Trade/Proprietary Name:	Cortez Needle Free IV Connector
Common/Usual Name:	Needle free, swab-able, IV Connector, and IV Sets
Classification Name:	CFR §880.5440 IV Administration Set (procode FPA)

3. Predicate Devices

ICU Medical CLC 2000 Swabbable IV Connector cleared under K973167, and the Critical Device Corporation Posi Flow™ NIMA™ cleared under K964918, and K964812.

4. Device Description

The Cortez is a two-way valve that permits needless access to an IV administration set. It can be connected to peripheral or central venous catheters or Y-sites. The Cortez is a normal closed valve that is opened by insertion of a standard male locking luer such as on an extension set, IV tubing or syringe tip to the female end of the Cortez IV Connector.

The Cortez IV Connector may be packaged individually and as attached as part of an extension set.

5. Intended Use

The Cortez Needle Free IV Connector is a Single use, sterile, non-pyrogenic, swab-able, needle free, bi-directional IV connector intended for use as an accessory to intravascular administration sets. The Cortez provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein or artery). The Cortez may replace the conventional y-site on a primary IV line as a continuous or intermittent connection. The Cortez also provides access for the withdrawal of fluids from a patient's vascular system.

6. Comparison to Predicate Devices

Characteristic	Mission Medical Devices Cortez (subject Device)	ICU Medical CLC 2000 Swabbable IV Connector (K973167)	Critical Device Corporation Posi Flow™ NIMA™ (K964918)
Product Labeling	Sterile, non-pyrogenic, single use, IV connector. Directions for use included.	Sterile, non-pyrogenic, single use, IV connector. Directions for use included.	Sterile, non-pyrogenic, single use, IV connector. Directions for use included.
Intended Use	The Cortez is a Single patient use, sterile, non-pyrogenic, swab-able, bi-directional valve intended for injection, as a gravity flow connector, and as an access port for withdrawal of fluids. For use with standard luer tapers.	The CLC2000 is a swab-able, bi-directional valve used to access any vein or artery or aspiration of fluids from the patient's vascular system.	For use as a needleless alternative to IV set injection ports. For use as part of a program to reduce needle stick injuries and the associated blood borne pathogens. For use for injection, as a gravity flow connector, and as an access port for withdrawal of fluids. For use with standard luer tapers. For single patient use.
Design	Swab-able, bi-directional, luer activated valve. The valve is normally in the closed position. When the luer opens the valve, a series of seals are displaced. When the valve is fully open, a fluid path is established. When the taper is removed, the valve automatically returns to the closed position. As it returns to the closed position, the seals within the valve provide a means for the valve to displace fluid through the male luer and out the distal end of the catheter, preventing blood from entering the lumen of the catheter.	Swab-able bi-directional luer activated valve. Closed system activated by a luer taper. The luer taper physically moves the poppet and o-rings, opening the valve. With the valve in the open position, fluid can be injected or withdrawn. The poppet and o-rings move to the sealed position automatically when the luer taper is removed. As the poppet and o-rings move to the sealed position, fluid is displaced through the male luer preventing blood flow from entering the lumen of the catheter.	Two-way valve that permits easy needle less intermittent and continuous access in IV therapy. Inserting a standard male luer taper, such as an extension set, IV tubing, or syringe to the female end of the adapter opens the normally closed valve.
Materials	Materials commonly used in similar applications.	Body–30% glass filled polyester Poppet–polycarbonate O-rings–silicone rubber Spring–stainless steel 302 Packaging – Medical Packaging grade fiber-free peelable paper lidding and pouching material.	Materials commonly used in similar applications.

7. Non-Clinical Performance Test Summary

The non-clinical performance test results demonstrate the Cortez IV Connector is equivalent to the predicate devices. Biocompatibility test results demonstrate the materials are biocompatible.

8. Substantial Equivalence Conclusion

The descriptive information and performance testing support the substantial equivalence claim between the Cortez IV Connector and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2001

Mr. Donald V. Canal
President
Mission Medical Devices
3525 Del Mar Heights Road #430
San Diego, California 92130

Re: K003254
Trade/Device Name: Cortez Needle Free IV Connector
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA
Dated: May 11, 2001
Received: May 14, 2001

Dear Mr. Canal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

K003254

Device Name: Cortez Needle Free IV Connector

Indications for Use:

The Cortez Needle Free IV Connector is a Single use, sterile, non-pyrogenic, swab-able, needle free, bi-directional IV connector intended for use as an accessory to intravascular administration sets. The Cortez provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein or artery). The Cortez may replace the conventional y-site on a primary IV line as a continuous or intermittent connection. The Cortez also provides access for the withdrawal of fluids from a patient's vascular system.

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Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cusenza
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003254